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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,126	07/23/2001	Padma S. Bagaria		2532

7590 06/10/2005

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,126	BAGARIA, PADMA S.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

PD

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 March 2005 has been entered.

2. Claims 10-16 are pending.

Claim Rejections - 35 USC § 112

3. Claims 10-16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 14 are confusing because it recites the deposition of a test sample either containing human hemoglobin antigen or not containing human hemoglobin and performing a test to determine the presence or absence of the hemoglobin antigen, respectively. In claim 10, for example, the test sample is recited as "containing a human hemoglobin antigen", if this is the case, why would there be a need for an assay to detect its presence? It is recommended that to obviate the confusing, the claims be

amended to recite that "a test sample *suspected* of containing human hemoglobin antigen" is added to the device.

Claim 13 is vague and indefinite with respect to the recitation of substituting the human hemoglobin antigen sample for a primate hemoglobin antigen sample since primate, by definite, includes human. Because the specification does not provide any guidance for what constitute a "primate", this claim is seen to be confusing because it does not further limit claim 10 from which it depends.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10, 12-14 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by May et al (US 5,656,503).

May teaches an assay device comprising a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device contains a labeled specific binding reagent for an analyte which is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which is

permanently immobilized in a detection zone on the carrier material (column 2, lines 4-21). The relative positioning of the labeled reagent and detection zone being such that liquid sample applied to the device can pick up labeled reagent and thereafter permeate into the detection zone. May also teaches that in an alternative embodiment, the labeled reagent is disposed in the protruding porous member where sample is applied (column 13, lines 32-36). The device also contains a control zone which is loaded with an antibody that will bind to the labeled antibody from the first zone (column 5, lines 9-15). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (column 3, lines 23-32). May teaches that an assay based on the principles taught in their reference can be used to determine a wide variety of analytes by choice of appropriate specific binding reagents. The analytes can be proteins, haptens or immunoglobins, etc. (column 9, lines 16-26). May specifically teaches that the ratio or levels of glycated hemoglobin (HbA) to unglycated (HbAo) or total (Hb) hemoglobin can be detected using antibodies specific to these hemoglobin antigens (column 9, lines 32-35).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Imrich et al (US 5,415,994).

See the discussion of May above. May differs from the instant invention in failing to specifically disclose that the immobilized capture antibody is an IgM.

Imrich discloses a similar device and method for detecting analytes in a sample. Imrich teaches immunoglobins for use as labeling reagents and as capturing reagents. Specifically, Imrich teaches that immunoglobulins may be antibodies or any isotypes, such as IgE, IgG or IgM, Fab fragments or the like (column 5, lines 15-20; lines 24-27 and lines 45-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the immunoglobulins disclosed by Imrich in the device and method of May for the detection of human hemoglobin antigens because May teaches the use of immunoglobins as labeled and capture reagents and Imrich made it clear that IgE, IgG or IgM are well known in the art for use as specific binding partners in an immunoassay.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/2/05